OCT 3 0 2003

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number _____ **Date Prepared: September 29, 2003**

Submitter's Name, Address and Contact Person

HandiNor as
Heiasvingen 65
N-1900 Fetsund
Norway

Contact Person: B. Chiponis
President, Lake Shore Consulting, LLC

Trade Name: HandiVipp

Common Name: Manual Wheelchair

Classification Name: Wheelchair, mechanical

Predicate Devices

The HandiNor HandiVipp wheelchair is substantially equivalent to the Sunrise Medical Quickie TSR (K952641).

Intended Use

The HandiNor HandiVipp is a manually operated device with wheels that is intended for medical purposes to provide mobility to physically challenged persons. The Handivipp is intended for indoor and outdoor use on firm surfaces free of climbing obstacles.

Technological Characteristics and Substantial Equivalence

Device Description

The HandiVipp comfort wheelchair, "HandiVipp", is a manually operated, self propelled or attendant propelled mechanical wheelchair. The HandiVipp 's intended use is to provide mobility to persons who may require specialized postural support and tilting features to assist in feeding and pressure relief. It is designed to meet the mobility and positioning needs of individuals with postural challenges e.g. Individuals with Scoliosis, Kyphosis, Cerebral Palsy, Muscular Dystrophy, Multiple Sclerosis and the like.

The HandiVipp frame is constructed from both 22 mm and 18 mm outside diameter (OD) round, mechanical, steel tubing. The side frames are of welded construction and are secured to the remaining frame members using screws and bolts. This device is a rigid wheelchair that incorporates a solid seating surface. The back frame can be folded by releasing a bolt. The seating plate (plain seat) has different hooks and different height levels on the hooks (short (standard), long and plain). This type of seat makes the chair easily adaptable to the various types of wheelchair cushions and seating systems.

Substantial Equivalence Comparison

The HandiNor HandiVipp wheelchair is substantially equivalent to the Sunrise Medical Quickie TSR (K952641).

Performance Data

The HandiNor HandiVipp wheelchair passed all technical requirements identified in ISO 7176: parts 1, 3, 5, 7, and 8.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2003

HandiNor USA, Inc.
C/o Ms. Barbara Chiponis
Lake Shore Consulting, LCC
17610 26th Avenue North
Plymouth, Minnesota 55447

Re: K033125
Trade/Device Name: HandiNor HandiVipp Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: September 29, 2003
Received: September 30, 2003

Dear Ms. Chiponis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

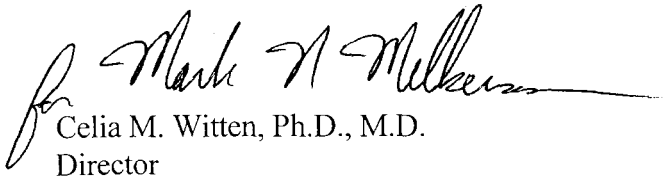
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name:

Indications for Use:

The HandiNor HandiVipp is a manually operated device with wheels that is intended for medical purposes to provide mobility to physically challenged persons. The Handivipp is intended for indoor and outdoor use on firm surfaces free of climbing obstacles.

The HandiNor HandiVipp is indicated for individuals with postural challenges e.g. Individuals with Scoliosis, Kyphosis, Cerebral Palsy, Muscular Dystrophy, Multiple Sclerosis, CVA, Spinal Chord injury, Spina Bifida, ALS and similar Neuromuscular and Musculoskeletal pathologies.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033125

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)